

CLAIMS

1. Equipment for controlling blood flow in an extracorporeal blood circuit, the said extracorporeal circuit having at least one blood treatment unit, at least one access  
5 branch extending between an area where blood is collected from a patient and the treatment unit, at least one peristaltic pump associated for operation with the said access branch of the extracorporeal circuit, and at least one return branch extending between the treatment unit and an area where the blood is returned to the patient, the said equipment comprising:
- 10 - at least a first sensor, designed to measure an arterial pressure (Part) in a portion of the said access branch upstream of the peristaltic pump, and to generate a corresponding first output signal proportional to the said arterial pressure (Part);
- at least a second sensor, designed to measure an angular velocity ( $\omega$ ) of the  
15 peristaltic pump and to generate a corresponding second output signal, proportional to the angular velocity of the said peristaltic pump;
- a memory designed to store at least one set value ( $Q_{set}$ ) of the desired blood flow through the said access branch, and a calibration function F in at least the following variables:
- 20 • v1, related to the angular velocity of the pump ( $\omega$ ),
- v2, related to the arterial pressure (Part) in the portion of the said access branch upstream of the peristaltic pump,
- v3, related to an actual flow of blood ( $Q_{actual}$ ) through the said access branch;
- 25 - at least one control unit, connected for operation to the said sensors and to the said memory, for receiving the said first and second output signals and for storing the corresponding measured values of arterial pressure (Part) and angular velocity ( $\omega$ ) in the said memory, the said control unit being capable of executing a control procedure comprising the following operations:
- 30 • calculating an actual flow value ( $Q_{actual}$ ) by applying the said memory-resident calibration function F to the values of angular velocity and arterial pressure (Part,  $\omega$ ) measured by means of the said sensors;
- comparing the said actual flow value ( $Q_{actual}$ ) with the said set flow value ( $Q_{set}$ );
- 35 • varying the angular velocity of the said peristaltic pump if the difference between the actual flow and the desired flow ( $Q_{actual} - Q_{set}$ ) lies outside a predetermined range.

2. Equipment according to Claim 1, characterized in that it also comprises a timer device connected for operation to the control unit, the said control unit being capable of executing the said control procedure at predetermined time intervals.
3. Equipment according to Claim 1, characterized in that it also comprises a user interface device capable of sending to the control unit at least one signal for activating the said control procedure and at least one signal for disabling it.
4. Equipment according to Claim 3, characterized in that the said user interface device is capable of receiving a manual setting of the set flow ( $Q_{set}$ ) and of transmitting this setting to the said control unit.
5. Equipment according to Claim 4, characterized in that the said control unit is capable of operating, selectively, either in a first operating mode, in which it waits for the said activating and disabling signals and the said manual setting of the set flow for activating the said control procedure, or in a second operating mode, in which it automatically executes the said control procedure during the said treatment.
6. Equipment according to Claim 1, characterized in that the said control procedure also comprises a step of verifying the stability of the said arterial pressure (Part).
7. Equipment according to Claim 6, characterized in that the step of verifying the stability of the said arterial pressure (Part) comprises the following sub-steps: measuring a first arterial pressure (Part1) at a predetermined instant ( $T1$ ), measuring a second arterial pressure (Part2) at an instant ( $T2$ ) following the said predetermined instant ( $T1$ ), comparing a difference between the first and second arterial pressures with a predetermined range of acceptability, waiting for a predetermined time interval and repeating the said steps of measuring and the said step of comparing if the difference between the first and second arterial pressures does not lie within the said predetermined range of acceptability, and continuing the said control procedure if the difference between the first and second arterial pressures lies within the said predetermined range of acceptability.
8. Equipment according to Claim 6, characterized in that the said step of verifying the stability of the arterial pressure is executed before the said step of calculating the actual flow.
9. Equipment according to Claim 1, characterized in that the said steps of calculating an actual flow value ( $Q_{actual}$ ), comparing the said actual flow value ( $Q_{actual}$ ) with the said set flow value ( $Q_{set}$ ), and varying the angular velocity of the said peristaltic pump succeed each other in time.

10. Equipment according to Claim 9, characterized in that there is provided, after the said step of comparing the said actual flow value ( $Q_{actual}$ ) with the said set flow value ( $Q_{set}$ ), and before the said step of varying the angular velocity of the said peristaltic pump, a step of comparing the Part with a threshold value considered critical for the patient being treated, and in that, if the pressure is below this threshold value, an exit is made from the algorithm and the operator is alerted by means of a warning message relating to the occurrence of a limit pressure condition.
11. Equipment according to Claim 9, characterized in that there is provided, after the said step of comparing the said actual flow value ( $Q_{actual}$ ) with the said set flow value ( $Q_{set}$ ), and before the said step of varying the angular velocity of the said peristaltic pump, a step of comparing the angular velocity with an acceptable maximum value which can be imparted to the pump.
12. Equipment according to Claim 1, characterized in that the calibration function  $F$  also has at least the following further variable:
- $V_4$ , related to a time ( $T_i$ ) elapsed from a start condition of the said control procedure,
- the said control unit being capable of determining a time which has elapsed between the said start condition and each instant in which the said control procedure is executed, and of calculating an actual flow value ( $Q_{actual}$ ) by applying the said memory-resident calibration function  $F$  to the value of the said time ( $T_i$ ) elapsed and to the values of angular velocity and arterial pressure ( $Part$ ,  $\omega$ ) measured by means of the said sensors.
13. Equipment according to Claim 1, characterized in that the calibration function  $F$  is of the type  $v_3 = \left[ \sum_{i=0...n} a_i \cdot (v_2)^{n-i} \cdot (v_1)^i \right] + C$ , where  $a_i$  and  $C$  are experimentally determined known parameters.
14. Equipment according to Claim 12, characterized in that the calibration function  $F$  is of the type  $v_3 = \left[ \sum_{i=0...n} \sum_{k=0...m} a_i \cdot b_k \cdot (v_2)^{n-i-k} \cdot (v_1)^i \cdot (v_4)^k \right] + C$ , where  $a_i$ ,  $b_k$  and  $C$  are experimentally determined known parameters.
15. Equipment according to Claim 13, characterized in that the calibration function  $F$  is of the type  $v_3 = a \cdot v_1 + b \cdot v_1 \cdot v_2 + c \cdot v_2 + d$ , where  $a$ ,  $b$ ,  $c$ ,  $d$  are experimentally determined known parameters.
16. Equipment according to Claim 14, characterized in that the said calibration function  $F$  is of the type  $v_3 = (a \cdot v_1 + b \cdot v_1 \cdot v_2 + c \cdot v_2 + d) \cdot f(v_4)$ , where  $a$ ,  $b$ ,  $c$ ,  $d$  are experimentally determined known parameters and  $f(v_4)$  is a function which is also known and experimentally determined in the variable  $v_4$ .

17. Equipment according to any one of the preceding claims, characterized in that the said memory is designed to store a plurality of calibration functions F1, F2, ... Fn, each at least in the variables v1, v2, v3, and each applicable to a corresponding one of a plurality of types of extracorporeal circuits.
- 5 18. Equipment according to Claim 17, characterized in that each of the said calibration functions F is also a function of the said variable v4.
19. Equipment according to Claim 18, characterized in that each of the said calibration functions F is also a function of at least one or more of the following further variables:
- 10 - v5, related to the geometrical characteristics of an access member connectable for operation to the said extracorporeal circuit;
- v6, related to the length of the portion of tube of the access branch upstream of the said peristaltic pump.
20. Equipment according to Claim 19, characterized in that the said function F
- 15 comprises two functions F' and F'', linked together with continuity, the first F' being valid in a first range of values of arterial pressure, and the second F'' being valid in a second range of values of arterial pressure which follows the said first range.
21. Software program comprising instructions for making the control unit capable
- 20 of executing the steps of the control procedure as claimed in one or more of the preceding claims.
22. Program according to Claim 21, characterized in that it is stored on a magnetic and/or optical recording medium.
23. Program according to Claim 21, characterized in that it is stored in a computer
- 25 memory.
24. Program according to Claim 21, characterized in that it is carried by an electric or electromagnetic carrier.
25. Program according to Claim 21, characterized in that it is stored in a read only memory.
- 30 26. Machine for treating blood in an extracorporeal circuit, characterized in that it comprises equipment for controlling the blood flow according to any one of Claims 1 to 20.
27. Machine for treating blood in an extracorporeal circuit according to Claim 26, characterized in that it is capable of carrying out one or more of the following
- 35 treatments:
- haemodialysis,
  - haemofiltration,

- haemodiafiltration,
- pure ultrafiltration,
- plasmapheresis.